



**IN THE UNITED STATES PATENT & TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND  
INTERFERENCES**

SERIAL NO. 09/691,671

FILED: OCTOBER 18, 2000

GROUP ART UNIT: 3763

INVENTOR: MICHAEL J. WILCOX

EXAMINER: KATHRYN THOMPSON

FOR: OPHTHALMIC IMPLANT

**APPELLANTS' APPEAL BRIEF**

Honorable Commissioner of Patents and Trademarks

Washington, D.C. 20231

Sir:

**REAL PARTY IN INTEREST**

The real party in interest in this appeal is MICHAEL J. WILCOX.

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**RELATED APPEALS AND INTERFERENCES**

There are no other appeals or interferences that will directly affect or be directly effected by, or have a bearing on, the Board's decision in the pending appeal.

**STATUS OF CLAIMS**

Claims 1-42, 46, and 51 have been cancelled. Claims 43, 44, and 47 were rejected and are appealed. Claims 45, and 48-50 were withdrawn from consideration and are appealed.

U.S.S.N.: 09/653,406  
Filed: September 1, 2000

**TRANSMITTAL OF DECLARATION FOR  
PATENT APPLICATION, STATEMENTS CLAIMING  
SMALL ENTITY STATUS, STATEMENT UNDER  
37 C.F.R. § 3.73(b), AND REQUEST FOR REFUND**

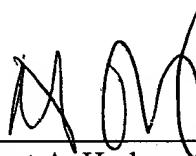
5. Check in the amount of \$65.00 for the small entity surcharge for late filing the Declaration for Patent Application.

Applicants have not yet received the Notice to File Missing Parts of Nonprovisional Application.

Applicants respectfully request a 50% refund of the \$1,472.00 filing fee in the application, a total of \$736.00, pursuant to 37 C.F.R. § 1.28.

Please charge any other fees due, or credit any overpayment, in connection with this matter to Deposit Account No. 01-2507. A duplicate of this transmittal is enclosed to facilitate this process.

Respectfully submitted,



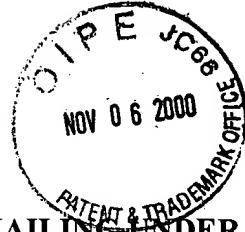
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Robert A. Hodges  
Reg. No. 41,074

Date: November 1, 2000

ARNALL GOLDEN & GREGORY, LLP  
2800 One Atlantic Center  
1201 West Peachtree Street  
Atlanta, Georgia 30309-3450  
404-873-8796  
404-873-8797 (fax)

U.S.S.N.: 09/653,406  
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**TRANSMITTAL OF DECLARATION FOR  
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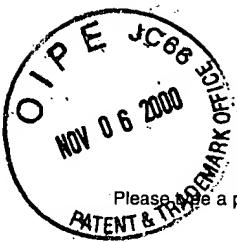
**CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)**

I hereby certify that this Transmittal of Declaration for Patent Application, Statements Claiming Small Entity Status, Statement Under 37 C.F.R. § 3.73(b), and Request for Refund, together with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to Box Missing Parts, Assistant Commissioner for Patents, Washington, D.C. 20231.

Chandra Russell

Chandra Russell

Date: November 1, 2000



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**DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)**

Declaration Submitted with Initial Filing       Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	RICE 100
First Named Inventor	Jennifer L. West
<b>COMPLETE IF KNOWN</b>	
Application Number	09 / 653,406
Filing Date	September 1, 2000
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**NITRIC OXIDE-PRODUCING HYDROGEL MATERIALS**

the specification of which

*(Title of the Invention)*

is attached hereto  
OR

was filed on (MM/DD/YYYY)  as United States Application Number or PCT International

Application Number  and was amended on (MM/DD/YYYY)  (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

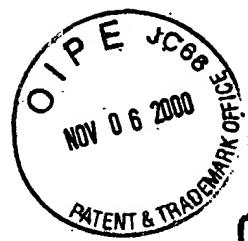
Application Number(s)	Filing Date (MM/DD/YYYY)	
60/152,054	09/02/1999	<input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

[Page 1 of 2]

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**DECLARATION — Utility or Design Patent Application**

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT International application designating the United States or listed below, and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)

Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02D attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:  Customer Number  →  *Plano Customer Number Bar Code Label here*

OR

Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number
Patrea L. Pabst	31,284		
Robert A. Hodges	41,074		
Kevin W. King	42,737		

Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to:  Customer Number or Bar Code Label  OR  Correspondence address below

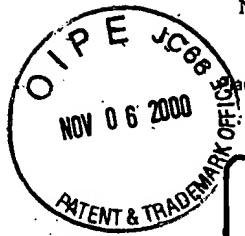
Name	Patrea L. Pabst		
Address	Arnall Golden & Gregory, LLP		
Address	2800 One Atlantic Center, 1201 West Peachtree Street		
City	Atlanta	State	GA
Country	United States	Telephone	(404)873-8794
		Fax	(404)873-8795

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor:	<input type="checkbox"/> A petition has been filed for this unsigned inventor		
Given Name (first and middle if any)		Family Name or Surname	
Jennifer L.		West	
Inventor's Signature	<i>Jennifer L. West</i>		
Residence: City	Houston Pearland	State	TX
Post Office Address	3523 Senova Drive		
Post Office Address			
City	Pearland	State	TX
	ZIP	77584	
	Country	USA	
<input type="checkbox"/> Additional inventors are being named on the <u>1</u> supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto			

Filed: September 1, 2000

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<b>DECLARATION</b>		<b>ADDITIONAL INVENTOR(S)</b> Supplemental Sheet Page <u>1</u> of <u>1</u>
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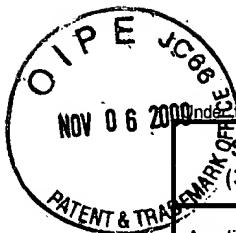
<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned Inventor					
Given Name (first and middle [if any])		Family Name or Surname					
Kristyn Simcha		Bohl					
Inventor's Signature						Date	10/31/00
Residence: City	Houston	State	TX	Country	USA	Citizenship	US
Post Office Address	4065 S. Braeswood, Apt. 243						
Post Office Address							
City	Houston	State	TX	ZIP	77025	Country	USA
<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned Inventor					
Given Name (first and middle [if any])		Family Name or Surname					
Inventor's Signature						Date	
Residence: City		State		Country		Citizenship	
Post Office Address							
Post Office Address							
City		State		ZIP		Country	
<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned Inventor					
Given Name (first and middle [if any])		Family Name or Surname					
Inventor's Signature						Date	
Residence: City		State		Country		Citizenship	
Post Office Address							
Post Office Address							
City		State		ZIP		Country	

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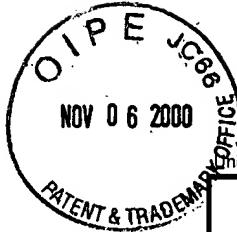
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<b>STATEMENT CLAIMING SMALL ENTITY STATUS</b> (37 CFR 1.9(f) & 1.27(d))--NONPROFIT ORGANIZATION		Docket Number (Optional) <b>RICE 100</b>
Applicant, Patentee, or Identifier: <u>Jennifer L. West and Kristyn Simcha Bohl</u> Application or Patent No.: <u>09/653,406</u> Filed or Issued: <u>September 1, 2000</u> Title: <u>NITRIC OXIDE-PRODUCING HYDROGEL MATERIALS</u>		
I hereby state that I am an official empowered to act on behalf of the nonprofit organization identified below: NAME OF NONPROFIT ORGANIZATION <u>Rice University</u> ADDRESS OF NONPROFIT ORGANIZATION <u>6100 Main</u> <u>Houston, Texas 77005</u>		
TYPE OF NONPROFIT ORGANIZATION: <input checked="" type="checkbox"/> UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION <input type="checkbox"/> TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 U.S.C. 501(a) and 501(c)(3)) <input type="checkbox"/> NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA (NAME OF STATE _____) (CITATION OF STATUTE _____) <input type="checkbox"/> WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 U.S.C. 501(a) and 501(c)(3)) IF LOCATED IN THE UNITED STATES OF AMERICA <input type="checkbox"/> WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA (NAME OF STATE _____) (CITATION OF STATUTE _____)		
I hereby state that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 CFR 1.9(e) for purposes of paying reduced fees to the United States Patent and Trademark Office regarding the invention described in: <input type="checkbox"/> the specification filed herewith with title as listed above. <input checked="" type="checkbox"/> the application identified above. <input type="checkbox"/> the patent identified above.		
I hereby state that rights under contract or law have been conveyed to and remain with the nonprofit organization regarding the above identified invention. If the rights held by the nonprofit organization are not exclusive, each individual, concern, or organization having rights in the invention must file separate statements as to their status as small entities and that no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).		
Each person, concern, or organization having any rights in the invention is listed below:		
<input type="checkbox"/> no such person, concern, or organization exists. <input checked="" type="checkbox"/> each such person, concern, or organization is listed below. <u>BioCure, Inc.; 2975 Gateway Drive, Suite 100, Norcross, Georgia 30071</u>		
I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))		
NAME OF PERSON SIGNING <u>Daryl S. Boudeaux, Ph.D.</u> TITLE IN ORGANIZATION OF PERSON SIGNING <u>Director, Office of Technology Transfer</u> ADDRESS OF PERSON SIGNING <u>Rice University MS-705, 6100 Main St, Houston, TX</u> SIGNATURE <u>Daryl S. Boudeaux</u> DATE <u>November 1, 2000</u>		

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**STATEMENT CLAIMING SMALL ENTITY STATUS  
(37 CFR 1.9(f) & 1.27(c))--SMALL BUSINESS CONCERN**

Docket Number  
RICE 100

Applicant, Pattee, or Identifier: Jennifer L. West and Kristyn Simcha Bohl

Application or Patent No.: 09/653,406

Filed or Issued: September 1, 2000

Title: NITRIC OXIDE-PRODUCING HYDROGEL MATERIALS

I hereby state that I am

the owner of the small business concern identified below:  
 an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF SMALL BUSINESS CONCERN BioCure, Inc.

ADDRESS OF SMALL BUSINESS CONCERN 2975 Gateway Drive, Suite 100  
Norcross, Georgia 30071

I hereby state that the above identified small business concern qualifies as a small business concern as defined in 13 CFR Part 121 for purposes of paying reduced fees to the United States Patent and Trademark Office. Questions related to size standards for a small business concern may be directed to: Small Business Administration, Size Standards Staff, 409 Third Street, SW, Washington, DC 20416.

I hereby state that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention described in:

the specification filed herewith with title as listed above.  
 the application identified above.  
 the patent identified above.

If the rights held by the above identified small business concern are not exclusive, each individual, concern, or organization having rights in the invention must file separate statements as to their status as small entities, and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization having any rights in the invention is listed below:

no such person, concern, or organization exists.  
 each such person, concern, or organization is listed below.

Rice University; 6100 Main, Houston, Texas 77005

Separate statements are required from each named person, concern or organization having rights to the invention stating their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

NAME OF PERSON SIGNING Andrew Maslaveckas

TITLE OF PERSON IF OTHER THAN OWNER Chief Operating Officer

ADDRESS OF PERSON SIGNING 2975 Gateway Dr., Suite 100, Norcross, GA

SIGNATURE

DATE November 1, 2000

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laterally therefrom to implement the formation of at least one aqueous filtration bleb in the tissue of the eyeball" of claim 43 with the "first strip-member 33" of Kousai. See Col. 6, ll. 9-10 and Figures 12-14 of Kousai. While the "second strip member" 34 of Kousai arguably has a similar appearance to Appellant's nidi-forming means 38, the strip member 33 does not even bear any physical resemblance to the "nidi-forming means" that is described in Appellant's specification and illustrated in the drawings. The cited strip member 33 of Kousai is grossly unrelated in purpose, function, structure and material to the recited nidi-forming means of claim 43. Clearly, the limitations "elongated fluid conducting conduit" and "nidi-forming means" of claim 43 do not equate to the apparatus disclosed by Kousai and relied upon by the examiner as the basis for the §102 rejections.

#### Claim 47

Claim 47 is dependant from claim 43 and adds the additional limitation of "anchoring means." This additional limitation in claim 47 is the basis for earlier stating that claim 47 does not stand or fall with claim 43. The anchoring means corresponds to the furcated distal ends 32, 132 and 242 of the implanted tube that serve the function of anchoring the implant in the sclera to prevent the migration of the implant into the anterior chamber of the eyeball. Claim 47 is allowable for the same reasons as those given for claim 43.

In rejecting claim 47 the examiner chose to equate "anchoring means" with the inserted catheter (35) of Kousai, depicted in his Figures 13 and 14. The cited catheter is not even a part of the insertion cannula disclosed by Kousai. It

manifestly is not "appended to the conduit to prevent the conduit from migrating from its placement site." The catheter 35 of Kousai is merely an illustrated example of a "rod-like medical instrument" that can be guided into a blood vessel by Kousai's introduction cannula. It is not, in any conceivable usage, an "anchoring means," as that term is defined in Appellant's specification. The catheter 35 of Kousai is a device by which fluids can be administered intravenously to a patient. No "anchoring means" is described or disclosed in the Kousai patent. The examiner's equation of "anchoring means appended to the conduit to prevent the conduit from migrating from its placement site" with an exemplary catheter that is independent from the Kousai apparatus is clear error.

#### The Error of the Section 102 Rejections

In order to anticipate a means-plus-function claim, the reference "must disclose the recited function *identically*." *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364 (C.A. Fed. 2002). The "nidi-forming means" of claim 43 corresponds to Appellant's structural elements 32(a), 38, 132(a) and 138, serving the function of forming a focal point, nest, or nidus, for capsule formation on the scleral surface of the eyeball. The strip-member 33 of Kousai (or for that matter, strip 34) is not intended to serve, does not serve and could not serve the function of forming nidi in an eyeball. It does not serve as a means to form a capsule in an eyeball. It could not be implanted in an eyeball. The purpose of Kousai's strips 33 and 34 is to split the introduction cannula after it has served its function of guiding the catheter so that it may be removed from the catheter, a function not even remotely analogous to the function of the nidi-forming means of claim

43. Not only is Kousai an inappropriate § 102 reference because it fails to show or disclose each element of the claimed combination, no one skilled in the art seeking to develop an eye implant for the treatment of glaucoma would find any suggestion or motivation to do so in the Kousai disclosure.

In the context of a means-plus-function claim, the invalidating prior art must disclose not simply a means for achieving the desired function, but rather the *particular structure* recited in the written description corresponding to that function, or an equivalent thereof. See *In re Donaldson Co., Inc.*, 16 F.3d 1189, 1193, 29 USPQ2d 1845, 1849 (Fed.Cir.1994). In addition to its notoriously disparate function, neither of the strips 33 nor 34 of Kousai are similar to the structure of the nidi-forming means detailed in the Appellant's specification, shown in his drawings and recited in the rejected claims. Basically, there is not a single redeeming feature in the examiner's section 102 rejection of claim 43 or the arguments made on behalf of the rejection.

The limitations of claims 43 and 47 clearly distinguish the combinations defined thereby from the Kousai introduction cannula by both function and structure. The rejection of these claims is erroneous under any set of standards for a section 102 rejection. Anticipation can only be established when a single prior art reference discloses each and every element of a claimed invention or its equivalent. *Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 772, 218 USPQ 781,789 (Fed. Cir. 1983). Kousai does not disclose an "elongated fluid conducting conduit," "nidi-forming means" or an "anchoring means" and, accordingly, rejection of claims 43 and 47 under § 102(b), must be reversed.

2. **The apparatus defined by claim 44 is not obvious and unpatentable over Kousai, US 4,883,468 in view of Odrich, US 6,471,666.**

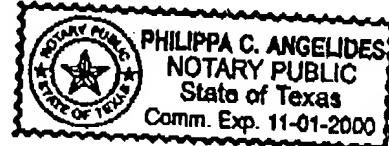
Claim 44 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Kousai, U.S. No. 4,883,468, in view of Odrich, U.S. No. 6,471,666. The examiner explains that:

"[I]t would have been obvious to one with ordinary skill in the art to use the teachings of Odrich to modify the invention of Kousai and add a ligature to Kousai in order to constrict the flow of aqueous in the tube."

However, it is inconceivable how it might be obvious to one skilled in the art to combine the ligature of Odrich with the introduction cannula of Kousai to bring into being the ophthalmic implant of Appellant, as defined in his claim 44.

Philippa C. Angelides  
Notary Public

My Commission expires: 11-01-2000



(Figures 8 and 9) and D (Figures 12,13 and 14). The “elongated fluid conducting conduit” and the “at least one nidi-forming means” of Claim 43 are found within all four species. Claim 45 reads on species B and C. Claims 48 and 49 read on species A, B, and C. Claim 50 reads on species B. The decision of the examiner to withdraw these claims from consideration for failure to provide a generic linking claim should be overturned in view of the above argument for allowability of generic claim 43.

## CONCLUSION

As required for a section 102 rejection, Kousai does not disclose each and every element of claim 43. The tubular body 43 of Kousai’s introduction cannula is not disclosed as a *elongated fluid conducting conduit* nor does it function as such. It is a guide for a rod-like medical instrument. The examiner’s equating of the first strip 33 (or even the second strip 34) of Kousai’s splittable introduction cannula to the *nidi-forming means that facilitates the formation of a bleb within the tissue of the eye*, of claim 43, is pure fiction and consequently an erroneous application of a reference to create a section 102 rejection. The manifest error continues when the examiner reads a catheter that is inserted into the blood vessel by the insertion cannula of Kousai as being an anchoring means, equivalent to the recited *anchoring means* of dependent claim 44.

Transferring the ligature 95 of the Ordich injectable glaucoma implant plate to the catheter insertion cannula of Kousai to defeat Appellant’s dependent claim 47 is a stretch of the motivation requirement of a proper section 103 rejection that is impossible to reconcile or justify on any ground.

For the specified reasons, the examiner's rejections of claims 43, 44 and 47 are outside of the parameters permitted by law and should be reversed. Such action by the Board is respectfully requested.

Following the Board's reversal of the rejection of claim 43, the Board is also requested to hold that claim 43 is generic to the elected species and to the species of the invention defined by withdrawn dependent claims 45 and 48-50. Accordingly the Board is respectfully urged to declare those claims allowable.

Overruling of the examiner's rejection of claims 43, 44 and 47, and the allowance of claims 45, and 48-50 is respectfully requested.

Dated: June 8, 2004

Respectfully Submitted



Richard W. Hanes  
Reg. No. 19,530

Hanes & Schutz, P.C.  
102 South Tejon Street, Suite 800  
Colorado Springs, CO 80903  
(719) 260-7900  
Docket No. 171.5050

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Vickie L. Hensley  
Vickie L. Hensley June 8, 2004